UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419 Master Dkt. 1:13-md-02419-FDS
THIS DOCUMENT RELATES TO: All Tennessee Actions.	Judge Rya Zobel

PLAINTIFFS' STEERING COMMITTEE'S RESPONSE TO THE TENNESSEE CLINIC DEFENDANTS' RESPONSE TO FDA'S MOTION FOR PROTECTIVE ORDER

The Plaintiffs' Steering Committee (the "PSC") hereby files this limited Response to the Tennessee Clinic Defendants' Response to FDA's Motion for Protective Order (Dkt. No. 1881, the "Response"), which, along with the Tennessee Clinic Defendants Motion to Compel (Dkt. No. 1775) seeks to compel the Food and Drug Administration ("FDA") to produce documents and sit for a 30(b)(6) deposition.[1] The FDA states in its pleading that it will produce documents but opposes sitting for a 30(b)(6) deposition until after the resolution of criminal trials.[2]

The PSC understands, based on conversations with counsel for the FDA, that the FDA will produce all of the documents produced originally as part of the Congressional investigation – an estimated 50,000 pages. The PSC maintains that, given the Tennessee Clinic Defendants' proffered reasons for needing discovery, that the documents from the FDA are sufficient and that a full 30(b)(6) deposition is unnecessary.

As a starting point, the PSC disagrees with the Tennessee Clinic Defendants' that the FDA is a key player in either the PSC's substantive claims or in the Tennessee Clinic

[1] Dkt. No. 1775 and 1881.

[2] Dkt. No. 1838.

Defendants' possible comparative fault defenses. Contrary to the claims of the Tennessee Clinic Defendants (who desire to make the FDA a scapegoat for this national tragedy), the FDA's oversight of compounding clinics has been the subject of considerable litigation and it is well known that a regulatory gap existed in the FDA's ability to regulate compounding pharmacies. In fact, the Ninth Circuit held that Section 503A of the Food, Drug and Cosmetic Act, which was enacted to give the FDA regulatory power over compounding pharmacies, was unconstitutional in its entirety.[3] The FDA also made it clear in both filings with federal court and in publicly available documents that compounding pharmacies posed unique risks when compared to traditional FDA regulated drug manufacturers. The Tennessee Clinic Defendants' attempts to rewrite this history and now blame the FDA for failing to sufficiently regulate NECC simply ignores this regulatory history.

In any event, the Tennessee Clinic Defendants set forth three reasons why they need a full 30(b)(6) deposition, all of which simply do not pass scrutiny.

First, the Tennessee Clinic Defendants claim they need a deposition of the FDA to rebut the plaintiff's allegation that individual clinics that purchased from NECC should have obtained information from the FDA prior to purchasing injectable steroids from NECC.[4] This is a red herring. To the extent that this issue is relevant, the key is what information the FDA had available to it, which the Tennessee Clinic Defendants can clearly discover if and when the FDA produces the documents it had its possession. A deposition is simply not necessary to answer this question. Further, plaintiffs can prove the fault of the Tennessee Clinic Defendants regardless of whether the FDA would have produced documents had the Tennessee Clinic

[3] *Western States Medical Center v. Shalala*, 238 F.3d 1090 (9th Cir. 2001), aff'd in part sub nom, *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002); *See also:* "The Special Risk of Pharmacy Compounding, May 2007, FDA Consumer Health Information, Available at http://www.pharmwatch.org/reports/compounding_risks.pdf.

[4] Dkt. No. 1881 at P. 5.

Defendants simply asked for them before buying MPA from NECC.[5] The Tennessee Clinic Defendants readily acknowledge in sworn testimony that prior to purchasing injectable steroids from NECC, the Tennessee Clinic Defendants did no due diligence whatsoever in investigating whether NECC was a safe and appropriate vendor. They did not attempt to contact the FDA, the Massachusetts Board of Pharmacy, or even ask NECC itself about its troubled regulatory history. They simply accepted at face value NECC's marketing materials, a decision that directly resulted in the deaths of many of their patients. Plaintiffs take issue with a host of problems with this cavalier attitude towards patient safety, only one of which is the fact that the Tennessee Clinic Defendants did not also seek readily available information from the FDA.[6]

Next, the Tennessee Clinic Defendants claim they need a deposition to establish its comparative fault defense that the FDA shares part of the blame for this national tragedy.[7] It is interesting that the Tennessee Clinic Defendants take this position, given that they were active participants with NECC in forging patient prescription order forms, one of the illegal activities that may have enabled NECC to elude FDA oversight.[8] In any event, the Tennessee Clinic Defendants can obtain the information necessary for a comparative fault defense from the documents within the FDA's possession; a discovery deposition will not aid this inquiry unless the FDA would be willing to admit that the documentary evidence supports the Tennessee Clinic Defendants' claims that the FDA erred in not shutting down NECC earlier. Given the FDA's testimony before Congress, a deposition will not elicit such testimony.

[5] In any event the information in the FDA's possession was clearly obtainable through a simple Freedom of Information Act request. *See generally* 5 USCS § 552.

[6] *See e.g.* Master Complaint Dkt. No. 545 at ¶ 234.

[7] Dkt. No. 1881 at P. 6.

[8] *See Medical Ctr. Pharm. v. Mukasey*, 536 F.3d 383 (discussing the FDA's regulatory oversight of compounding pharmacies and noting that FDA's oversight of compounding pharmacies was clearer for compounding pharmacies that acted as drug manufacturers as opposed to common pharmacy dispensers which dispense drugs pursuant to valid patient-specific prescriptions).

Finally, the Tennessee Clinic Defendants claim they need a deposition to support claims of comparative fault alleged against other parties and non-parties, namely NECC itself.[9] NECC's liability, however, is easily established based on the thousands of pages of documents already made available. Inquiry into the FDA's knowledge about NECC's practices is simply duplicative discovery over the information already made available to the Tennessee Clinic Defendants. Courts routinely deny such duplicative discovery, especially in instances where the duplicative discovery is obtained at the expense of a non-party.[10] And to the extent that documents produced by the FDA suggest the comparative fault of others, one would expect the Tennessee Clinic Defendants would then want to depose the others potentially at fault, not the FDA.

The PSC takes no position on the other issues raised in the Response, but it did believe it was necessary to rebut the claims addressed above given the PSC's familiarity (and the FDA's relative disadvantage as a non-party) with the claims at issue in this litigation.[11]

Dated: May 27, 2015

Respectfully submitted,

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[9] Dkt. No. 1881 at P. 6.

[10] *See e.g., Medical Components, Inc. v. Classical Medical, Inc.*, 210 F.R.D. 175, 180 n. 9 (M.D.N.C.2002) ("The current generally prevailing view is that the Court may first consider whether information should be obtained by direct discovery from a party, as opposed to from a non-party, and that the court should give special weight to the unwanted burden thrust upon non-parties when evaluating the balance of competing needs.").

[11] The Tennessee Clinic Defendants also assert a number of unfounded allegations related to the PSC's alleged attempts to resist discovery. Dkt. No. 1881 at P. 2. The PSC disagrees with this characterization but will not take the bait and unnecessarily burden the Court by rebutting every irrelevant claim contained in the Response.

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CERTIFICATE OF SERVICE

I, Benjamin A. Gastel, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: May 27, 2015

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